UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,670	12/14/2001	Agathe Subtil	216907US0X	4884

22850 7590 05/05/2006

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,670	SUBTIL ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-10 and 30-47* is/are pending in the application.

4a) Of the above claim(s) *30-33 and 38-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-10,34-37 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 June 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Appeal Brief filed February 3, 2006 is acknowledged. Claims 7-10 and 30-47 are pending the application. Claims 30-33 and 38-43 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Upon further consideration the finality of the Office action mailed January 27, 2006 has been withdrawn and a non-final action is set forth below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 7-10, 34-37 and 44-47 are rejected under 35 U.S.C. 103(a) as unpatentable over Graffais et al *(U.S. Patent No. 6,559, 294 B1 published May 6, 2003)* in view of Demers et al *(WO 99/58714, published November 18, 1999)* and further in view of Kalman et al *(Nature Genetics, Volume 21, April 1999).*

Claims 7-10, 34-37 and 44-47 are drawn to a method for identifying a secreted *Chlamydia* polypeptide wherein said method comprises (a) providing a recombinant expression vector containing at least DNA coding for the peptide of interest, (b) transforming a Gram-negative strain containing a type III secretion pathway with said recombinant vector; (c) expressing said vector in said Gram-negative transformed

strain; and (d) detecting the secretion of said DNA expression product; wherein the secretion of said expression product indicates that it corresponds to a secreted *Chlamydia* polypeptide.

Graffais et al teach a method of identifying a secreted *Chlamydia polypeptide* comprising using a vector and or cell transformed with said vector and /or transgenic animal comprising one or more transformed cells containing nucleotide sequence encoding a *Chlamydia pneumoniae* secreted polypeptide involved in a type III secretion pathway (columns 50 and 51). Graffais et al teach that the vectors of the invention comprise the elements necessary to allow expression and/or secretion of said nucleotide sequences in a give host (column 46). Graffais et al teach that a preferred host cell for the expression of the proteins of the invention is a gram-negative bacteria (column 48). Graffais et al teach that detection of secreted polypeptides can be detected by techniques known in the art (column 40).

Graffais et al do not teach the claim limitation "wherein said gram-negative strain containing a type III secretion pathway is a *Shigella* strain".

Demers et al teach that *Shigella* bacteria are gram-negative organisms that contain type III secretion machinery (page 1).

Demers et al nor Graffais et al teach *Chlamydia* polypeptides selected from the group consisting of CPn0105, CPn0287, CPn0330, CPn0334 CPn374, CPn379, CPn705, CPn0710, CPn0711, CPn0820, CPn821, CPn1016 and CPn1022.

Kalman et al teach *Chlamydia* polypeptides from *Chlamydia pneumoniae* and *C. trachomatis* genomes (see the Title). Kalman et al teach for example, CPn0105

(CT016) which is a GcpE protein that is conserved in both the *Chlamydia pneumoniae* and *C. trachomatis* genomes (Table 1, page 5). Kalman et al teach that comparative analysis of the *Chlamydia pneumoniae* and *C. trachomatis* genomes will significantly enhance the understanding of both pathogens and identification of genes shared between the two species supports the requirement for capabilities in biological systems that have, over long-term association with mammalian cells, evolved to reduce metabolic capacities while optimizing survival, growth and transmission of these unique pathogens (page 385).

It would be *prima facie* obvious at the time the invention was made to identify polypeptides as taught by Kalman et al using the method of identifying polypeptides using Type III secretion machinery as combined above because Graffais et al teach that secreted *Chlamydia* polypeptides identified using vectors and/or cells transformed with said vector and /or transgenic animal comprising one or more transformed cells containing nucleotide sequence encoding a *Chlamydia pneumoniae* secreted polypeptide involved in a type III secretion pathway. It would be expected barring evidence to the contrary, that identifying *Chlamydia* polypeptides would significantly enhance the understanding of *Chlamydia* pathogens and identification of genes shared between the two *C. pneumoniae* and *C. trachomatis* which enhance the understanding of both pathogens as well as be important in terms of virulence and pathogenesis capabilities of each pathogen.

3. Claims 7-10, 34-37 and 44-47 are rejected under 35 U.S.C. 103(a) as unpatentable over Stephens et al *(U.S. Patent No. 6,822,071 B1 published November 23, 2004)* in view of Demers et al *(WO 99/58714, published November 23, 2004).*

Claims 7-10, 34-37 and 44-47 are drawn to a method for identifying a secreted *Chlamydia* polypeptide wherein said method comprises (a) providing a recombinant expression vector containing at least DNA coding for the peptide of interest, (b) transforming a Gram-negative strain containing a type III secretion pathway with said recombinant vector; (c) expressing said vector in said Gram-negative transformed strain; and (d) detecting the secretion of said DNA expression product; wherein the secretion of said expression product indicates that it corresponds to a secreted *Chlamydia* polypeptide.

Stephens et al teach a method of identifying a secreted *Chlamydia polypeptide* comprising using a vector and transforming the cells into host cells (columns 15 and 16). Stephens et al teach that the vectors of the invention comprise the elements necessary to allow expression and/or secretion of nucleotide sequences in a host (column 16). Stephens et al teach that such bacteria host cell such as *E. coli* can be used for the expression of the proteins of the invention (column 16). Stephens et al teach that detection of *Chlamydia* gene expression can be performed in a variety of ways (column 15). Stephens et al teach a secreted protein, for example, CPn105 (CT016)(a polypeptide of the elected species) (see Table 2, columns 27-28).

Stephens et al do not teach the claim limitation "wherein said gram-negative strain containing a type III secretion pathway is a *Shigella* strain".

Demers et al teach that gram-negative bacteria contain type III secretion machinery and can secrete proteins via this machinery (pages 1 and 2). Demers et al teach that *Shigella* species can be used to secrete proteins (pages 1 and 6-9).

It would be *prima facie* obvious at the time the invention was made to modify the method of identifying *Chlamydia* polypeptides as taught by Stephens et al by using the Type III secretion machinery of Shigella to secrete a desired *Chlamydia* polypeptide because Demers et al has teach that polypeptides can expressed using the type III secretion pathway of gram-negative bacteria (e.g. *Shigella* species). It would be expected barring evidence to the contrary, that the type III secretion pathway of *Shigella* would be effective in secreting *Chlamydia* polypeptides.

Status of Claims

4. No claims are allowed.

5. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (571) 272-8300.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
April 29, 2006

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600